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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/019,571	12/31/2001	Etsuro Ogata	04853.0086	7887

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EXAMINER	
LI, RUIXIANG	

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 09/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/019,571	OGATA ET AL.	
	Examiner	Art Unit	
	Ruixiang Li	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 July 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1, 3-10, 12-14, 18, 23, 24, and 26-30* is/are pending in the application.

4a) Of the above claim(s) *4-8, 12, 13, 18, 23, and 24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,9,10,14 and 26-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of Application, Amendments, and/or Claims

The Request filed on 07/06/2005 for Continued Examination (RCE) under 37 CFR 1.114 of Application 10/019,571 is granted. An action on the RCE follows.

Applicants' amendment filed on 07/06/2005 has been entered. Claims 1, 14, 26, and 30 have been amended. Claims 1, 3, 9, 10, 14, and 26-30 are currently under consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Withdrawn Objections and/or Rejections

The rejection of claims 1, 3, 9, 10, 14, and 26-30 under 35 U.S.C. 112, 1st paragraph for scope of enablement has been withdrawn in view of amended claims.

The rejection of claims 1, 3, 9, 10, 14, and 26-30 under 35 U.S.C. 112, 1st paragraph for written description has been withdrawn in view of amended claims.

The rejection of claims 1, 3, 9, 10, 14, and 26-30 under 35 U.S.C. 102(e) as being anticipated by Sato et al. (US2002/0165363 A1, Publication Date: November 7, 2002;

earliest priority date: May 15, 1997) has been withdrawn in view of amended claims and Applicants' argument.

Claim Rejections Under 35 USC § 102

(i). The rejection of claims 1, 3, 9, 10, 14, and 26-30 under 35 U.S.C. 102(b) as being anticipated by Grunfeld et al. (WO 96/39184, December 12, 1996) as set forth in the record is maintained. For clarity, the rejection is set forth below.

Claims 1, 3, 9, 10, 14, and 26-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Grunfeld et al. (WO 96/39184, December 12, 1996).

Grunfeld et al. teach treatment of systematic inflammatory response syndrome, including septicemia (1st paragraph of page 1; line 2 of page 3), with an anti-PTHrP antibody (Abstract; lines 5-26 of page 1). The antibody includes a humanized antibody and a human antibody (bottom of page 5). The anti-PTHrP antibody inhibits, by its nature, the binding of PTHrP to the PTHrP type 1 receptor because the binding of anti-PTHrP antibody to PTHrP could mask the binding site of a PTHrP molecule for its receptor. The septicemia, which is listed in canceled claim 11 as one of the diseases mediated by PTHrP-cytokine (IL-6), necessarily reduces quality of life (QOL) of patients. Thus, the reference of Grunfeld et al. meets the limitations of claims 1, 3, 9, 10, 14, and 26-30.

(ii). Response to Applicants' argument

Beginning at the bottom of page 10 of Applicants' response filed on 07/06/2005, Applicants argue that Grunfeld et al. do not clearly disclose or teach a humanized or human antibody and do not claim a humanized or human antibody. Applicants submit that the specification's reference to "other forms of antibodies" does not convey sufficient information so that a person skilled in the art is placed in possession of the claimed invention. Applicants further submit that the only antibodies taught by Grunfeld et al. are goat and rabbit antibodies.

Applicants' argument has been fully considered, but is not deemed to be persuasive because Grunfeld et al. clearly disclose a humanized or human antibody. For example, at page 5, lines 29-37, Grunfeld et al. states " the polyclonal or monoclonal antibodies may be raised in rabbits, mice, or other animals or tissue cultured cells or **can be products of cells of human origin**. They may also be produced of recombinant DNA technology either in a form identical to that of the native antibody or as chimeric molecules, **constructed by recombination of antibody molecules of man and animal origins** or in other forms chosen to make the antibodies most suitable for use in therapy". It is noted that a humanized antibody is referred to in the art as "reshaped human antibody", in which the complementarity determining regions of an antibody of a non-human mammal (e.g., a mouse) are grafted to those of a human antibody (Sato et al., US2002/0165363 A1, Publication Date: November 7, 2002; earliest priority date:

May 15, 1997, especially [0047]). In this context, Grunfeld et al. teach in actuality a humanized antibody in view of the instant disclosure.

Moreover, in the background of the invention, Grunfeld et al. teach the therapeutic use of a human antibody (from the bottom of page 1 to top of page 2). For example, beginning at page 1, line 35, Grunfeld et al. state: "Murine and human monoclonal antibodies directed against the core lipopolysaccharide of the endotoxin have been reported to exert protection during Gram-negative bacterial sepsis in animals". Beginning at page 2, line 12, Grunfeld et al. state: "In addition, human monoclonal antibodies to *p. aeruzinosa exotoxin A* and exoenzyme S have been described as useful for this purpose".

Accordingly, the teachings of Grunfeld et al. anticipate claims 1, 3, 9, 10, 14, and 26-30.

Claim Objections

(i). Claim 9 is objected to because of the following informalities: the word, "septicemia", is missing in line 1.

(ii). Claims 9, 10, 28, and 29 are objected to because they recite non-elected subject matter (species). Since independent claims 1 and 26 are drawn to a method of treatment of septicemia with a PTHrP antibody, PTH-cytokine cascade does not appear to be related to septicemia. Thus, only PTHrP-cytokine cascade should be recited in

claims 9 and 28. In addition, it is suggested that only the cytokines that are involved in septicemia be listed in claims 9, 10, 28, and 29.

Appropriate correction is required.

Conclusion

No claims are allowed.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruixiang Li whose telephone number is (571) 272-0875. The examiner can normally be reached on Monday through Friday from 8:30 am to 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (571) 272-0829. The fax number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you

have questions on access to the Private PAIR system, please contact the Electronic Business Center (EBC) at the toll-free phone number 866-217-9197.

Ruixiang Li

Ruixiang Li, Ph.D.
Primary Examiner
August 30, 2005